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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/625,384	07/26/2000	Richard A. Mueller	C-3128/1	8631

7590

12/04/2001

Pharmacia Corporation
Corporate Patent Department
P O Box 5110
Chicago, IL 60680

EXAMINER

ROBINSON, BINTA M

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 12/04/2001

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/625,384

Applicant(s)

Mueller Et. Al.

Examiner
Binta Robinson

Art Unit
1625



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-99 is/are pending in the applica

4a) Of the above, claim(s) 1-18 and 38-99 is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 19-37 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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DETAILED ACTION

Election/Restriction

The applicant's election of species at paper no. 6 is noted. The examiner will now use this species as a reference point to create a natural genus based on a liberal interpretation of the doctrine of legal and chemical equivalence and restriction will be required under U. S. C. 121.

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 19-37, drawn to the compound of formula I where R1 is all moieties not containing a heterocyclic ring, t is 2, R2 is arylthioalkyl, a method of treating classified in class 546, subclass 146 and class 514 subclass 307.
 - II. Claims 1-99, drawn to the compounds of formula I where R1, R20 and R21, R21, and R2 are all other moieties not covered in group I, and a method of treating classified in various classes, subclasses.

The inventions are distinct, each from the other because of the following reasons: In the instant case, the different inventions have achieved a separate status in the art, have separate fields that aren't coextensive, and are capable of supporting separate patents. Further, a prior art reference that would anticipate the claims under 35 U. S. C. 102 (b) would not render obvious the same claim (s) under 35 U. S. C. 103 (a) with respect to another member. Searching the entire genus would be a burden on the USPTO in terms of time and expense. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of

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their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

2. Claims 1-18 and 38-99 as well as the unelected portions of claims 19-37 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

100ep

Claim 33 in part is rejected under 35 U. S. C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility, one skilled in the art clearly would not know how to use the claimed invention. Inhibiting a retroviral protease is a mechanism. The disease being treated by this inhibition is not stated. The specification must contain one practical utility in currently available form. The inhibition of an enzyme must be related to a disease that needs to be improved and this disease needs to be

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recited. There is no reasonable assurance that these will have all of the alleged properties since applicant does not show these compounds encompassing the wide Markush group are correlated to the treatment of specific diseases. The applicant is referred to *In re Fouche* 169 USPQ 429 ccpa, 1971, MPEP 716.02 B. The applicant is also referred to *In re Wands*, 858 F. 2d 731, 737, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in *Ex parte Foreman* 230 USPQ 546 (Bd. Of App. And Inter. 1986).

Thus the fifth Wands factor of the predictability in the art of these compounds in treating certain diseases, the sixth Wands factor of the amount of direction provided by the inventor in terms of the use of these compounds for the treatment of specific diseases, and seventh Wands factor of the provision of working examples of the use of these compounds in the treatment of specific diseases are not satisfied. Additionally, the eighth Wands factor of the quantity of experimentation needed to make or use the invention based on the content of the disclosure is not satisfied. Undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claims are enabled by the instant specification.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claims 30, 34, and 37 in part rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 30 in part is indefinite, because the phrase "t and y" on line 3 of page 184 is written through the formula.

B. Claim 34 in part, the phrase "a retroviral infection" in line 1, page 184 is indefinite. The phrase is so broad. Which retroviral infection is the applicant claiming?

C. In claim 37, line 3, page 185, the phrase "in combination with other drugs" is indefinite. Which other drugs is the applicant claiming?

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-37 in part are rejected under 35 U.S.C. 102(b) as being anticipated by Jungheim et. al.

(See Reference A). Jungheim et. al. teaches the instant compound, 3-Isoquinolinecarboxamide,

N-(1,1-dimethylethyl)-2-[3-[[3-[(4-fluorophenyl)sulfonyl]-2-[(methylsulfonyl)amino]-1-

oxopropyl]amino]-2-[3S-[2[2S*(R*), 3 alpha, 4e.be. At columns 1-68, see the instant compound

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-37 in part are rejected under 35 U.S.C. 103(a) as being unpatentable over CA reference Jungheim et. Al. (See Reference A)

Jungheim teaches the instant compounds as disclosed in Formula I where R can independently be $R^0-NHCH_2(R^2)C(O)$, R^2 is $-(CH_2)_y-X-R^{2a}$ where y is 0, X is $S(O)_2$, R^{2a} is aryl, A is CH_2 , Y_1 is heterocycle, R^3 is $-C(O)NR^4R^4$, where R^4 is H. At column 65, see the instant compound.

The difference between the prior art references and the instantly claimed compounds is that a generic formula is claimed in the application versus a subclass of compounds. This situation falls within the Genus-Species Guidelines.

It would have been obvious to one of ordinary skill in the art to select various known radicals within a genus to prepare structurally similar compounds. Accordingly, the compounds are deemed unpatentable therefrom in the absence of a showing of unexpected results for the claimed compounds over those of the prior art.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703)306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-for After Final Communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.



December 3, 2001



ALAN L. ROTMAN
PRIMARY EXAMINER